Need for additional research

As noted above, the quality of studies that have been performed to evaluate FDG PET could be significantly improved. In all of the clinical conditions for which Medicare will now provide coverage, and for the remaining oncologic and other clinical uses, there is still a need for additional high quality clinical studies. HCFA is aware that there is limited public and private funding available for clinical research, particularly for studies that evaluate the clinical utility of promising technologies that emerge from basic research. For this reason, Medicare has recently implemented a policy for paying the routine costs for patients in clinical trials. The policy is aimed at increasing participation of Medicare patients in diagnostic and therapeutic trials, and well-designed evaluations of PET would be likely to qualify for coverage under this policy. For technologies of unique public health importance, HCFA will consider paying for the cost of experimental interventions in the context of clinical trials. This has been done in the past for several NIH-sponsored clinical trials that will provide critical evidence for developing HCFA coverage policy.

HCFA encourages the PET community to consult with experts in the evaluation of diagnostic technology in designing studies that will improve the empirical information available to clinicians and patients who use PET. HCFA staff is also available to meet with scientists and clinicians involved in the development of novel technologies in order to provide general advice on study design. We have initiated discussion with the National Cancer Institute to explore the possibility of collaborating with the PET community on these high priority studies, and look forward to continuing those discussions. More consistent conduct of these studies will be the most efficient way for Medicare to continue to expand coverage for novel beneficial technologies in a time frame that better matches the pace at which they are being developed.

Consideration of remaining indications

The current request for broad coverage received on July 10, 2000 is now considered closed by virtue of this coverage decision. Our review of all evidence submitted and additional evidence gathered supports the conclusion that the request for broad coverage is denied. Within that broad coverage request, we did find sufficient evidence to support coverage for the conditions described earlier in this document. The use of PET for clinical indications not addressed in this decision memo or previous Medicare coverage policies will remain non-covered. We encourage the requesters or others to submit new separate coverage requests for use of FDG PET in any additional clinical conditions that they believe would meet the coverage standards described in this document.